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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/827,937	04/09/2001	Yi Li	1488.1220003/EKS/EJH	8058

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EXAMINER	
CHANDRA, GYAN	
ART UNIT	**PAPER NUMBER**
1646	

DATE MAILED: 05/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/827,937	LI ET AL.	
	Examiner	Art Unit	
	Gyan Chandra	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 March 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *23-35 and 37-78* is/are pending in the application.

4a) Of the above claim(s) *75-78* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *23 -35 and 37-74* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *09 April 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

RD

DETAILED ACTION

Status of Application, Amendments, And/Or Claims

Claim 36 is canceled. The amendment of claims 29, 30, 32, 33, 55, 56, 58 and 59 has been made of record.

Claims 23-35 and 37-78 are pending. Claims 75 -78 are withdrawn from further consideration as being drawn to a nonelected Invention.

Claims 23 -35 and 37-74 are examined on the merit to the extent that they read on the elected Invention.

The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior office action.

Election / Restriction

Applicants' note that if the product claim of Group I is allowable then the process claims of Group II should be rejoined together is acknowledged.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be

fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Claim Rejections - 35 USC § 101 and 112, First Paragraph

The rejection of claims 23-35 and 37-74 under 35 U.S.C. 101 as not supported by either a specific and substantial asserted utility or a well established utility is maintained. Applicants' arguments have been fully considered but they are not persuasive.

The claims are drawn to an isolated antibody/antibody fragment: (i) which specifically binds to the polypeptide of amino acids 1-342 or 2-342 of SEQ ID NO: 2, (ii) which specifically binds to the polypeptide encoded by the human cDNA in ATCC deposit NO.209003, and (iii) which specifically binds to the mature polypeptide produced upon cellular expression of the polypeptide encoded by the human cDNA in ATCC Deposit NO: 209003. Further, claims are drawn to a method of producing isolated antibody and antibody fragments.

The bases for these rejections is set forth at page 7-17 of the previous Office Action (mailed 23 December, 2004).

Applicant argues that the specification discloses the use of antibody as an antagonist to the polypeptide of amino acids 1-342 or 2-342 of SEQ ID NO: 2 and the specification discloses use of antagonists for treating various diseases, including myocardial infarction. The specification discloses that the polypeptide of amino acids 1-342 or 2-342 of SEQ ID NO: 2 has about 25% identity and 49% similarity to the EBI-1 gene over an approximately 350 amino acid stretch, page 7. EDG-2 (G protein coupled receptor of SEQ ID NO: 4) has about 54% identity and 73% similarity to the EDG-1 orphan G-protein coupled receptor, page 7. Both EBI-1 and EDG-1 are found in a variety of tissue and are themselves considered orphan receptors. Applicant further argues that the specification (paragraph 0035) indicates that " GPCR molecule and their associated G-proteins have been implicated in the coupling of visual pigments to cGMP phosphodiesterase, PI turnover, adenylyl cyclase singnal ...." and suggests that novel GPCR molecules may prove useful in research and development.

However, as was set forth in Brenner v. Manson, 383 U.S. 519 (1966), the instant invention lacks a specific and substantial real world utility absent elucidation of the biological function of the disclosed protein agonist which the claimed antibody is directed and any role that the antibodies identified as modulators of the protein would play in modulation or identification of any disease state associated with that biological function. Without further research and experimentation, the claimed antibodies do not provide an immediate benefit to the public. The biological research contemplated using applicants' antibodies is to take place sometime in the future, only after elucidation of the biological role of the polypeptide of amino acid sequence of SEQ ID NO: 2.

However, no disclosure is provided within the instant specification as to any specific biological function of the polypeptide having SEQ ID NO: 2 or any specific disease where the claimed invention could be used. Speculating a function of a protein merely based on that EBI-2 is a GPCR and would have some use in research and development is not asserted utility.

Applicant argues that there is at least one specific utility for the claimed antibody. Applicants' argument has been fully considered but is not found to be persuasive. Applicant argues that the claimed antibody can be used for the detection of heart disease among the diseases. The specification (pg. 23, [0097] discloses that " antagonists have been employed for treatment of hypertension, angina pectoris, myocardial infarction, ulcers, asthma, allergies, psychoses, depression, migrain, vomiting, stroke, eating disorders, migraine headaches, cancer and benign prostatic hypertrophy". However, the instant specification does not disclose that EBI-2 is associated with a particular disease. Applicant argues that the specification (paragraph 0032) discloses that EBI-2 is identified from an umbilical vein endothelial cells, neutrophil leukocytes cells and corpus callosum cell and one of ordinary skill in the art would logically know the function and utility of a gene. A cDNA expression library is representative of mRNAs expressed in that tissue. Mere presence of a mRNA in a tissue does not provide function of a gene to one of skill in the art. One of skill in the art then has to find what this gene does which leads in to further experimention. Therefore, presence of EBI-2 in an umbilical vein endothelial cells, neutrophil leukocytes cells, corpus callosum cell or other cells does not establish a nexus between the claimed

antibody against EBI-2 and specific and substantial utility without significant further research.

Applicant argues that the Applicant has identified for the invention that can be viewed as providing a public benefit should be considered as sufficient. This has been fully considered but is not found to be persuasive. Applicants assert that the specification [0035, page 8, 0097, page 23, 0098, page 24, 0099, page 24], discloses a role of the claimed invention in potential diverse therapeutic and diagnostic applications including mental disorders, cancer, migraine, eating disorders, asthma, heart disease, psychoses, restenosis, Alzheimer's disease, Parkinson's disease, atherosclerosis and a number of others. The applicants' disclosure provides a large list of diseases allegedly associated with the polypeptide of SEQ ID NO: 2, but fails to disclose the specific role of the disclosed protein in any of these diseases. Further, Applicants point to publications by Hollopeter et al. (2001) and Dorsham et al (2004) that describe a role of EBI-2 GPCR in platelet aggregation. Both publications (Hollopeter and Dorsham) are after the filing date and Applicants have failed to disclose an asserted, substantial and specific utility of their invention in the specification at the time of filing the instant application.

In re Kirk, 153 USPQ 48, 53 (CCPA 1967) quoting the Board of Patent Appeals, " We do not believe that it was the invention of the status to require the Patent Office, the courts, or the public to play the sort of guessing game that might be involved if an applicant could satisfy the requirements of the statutes by indicating the usefulness of a claimed compound in terms of possible use so general as to be meaningless and then, after his research or that of his competitors has definitely ascertained an actual use for

the compound, adducing evidence intended to show that a particular specific use would have been obvious to men skilled in the particular art to which this use relates."

Therefore, Applicant's assertion that the claimed antibody can be used in potential diverse therapeutic and diagnostic applications including mental disorders, cancer, migraine, eating disorders, asthma, heart disease, psychoses, restenosis, Alzheimer's disease, Parkinson's disease, atherosclerosis and a number of others specification [0035, page 8, 0097, page 23, 0098, page 24, 0099, page 24], does not establish an asserted, specific, and real world utility.

The rejection of claims 23-35 and 37-74 under 35 U.S.C. 112, first paragraph for lacking enablement because the invention lacks utility is maintained for the reasons set forth above.

***Claim Rejections - 35 USC § 112*, second paragraph**

The rejection of claims 29 and 30 under U.S. ***35 USC § 112***, second paragraph, as being vague and indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, has been withdrawn persuasive to applicants' amendment of the claims.

Claim Rejections - 35 USC § 112, First Paragraph – Written Description

The rejection of claim 36 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the

application was filed, had possession of the claimed invention is withdrawn persuasive to applicant's cancellation of the claim.

Claim Rejections - 35 USC § 112, First Paragraph – enablement

The rejection of claim 36 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention is withdrawn persuasive to applicant's cancellation of the claim.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gyan Chandra whose telephone number is (571) 272-2922. The examiner can normally be reached on 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on (571) 272-0829. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gyan Chandra
AU 1646
05 May 2005

JANET ANDRES
PRIMARY EXAMINER